# In the United States Court of Federal Claims Office of special masters No. 21-1359V

DONNA FULBRIGHT,

Chief Special Master Corcoran

Petitioner,

٧.

Filed: March 27, 2025

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent.

## **RULING ON ENTITLEMENT**<sup>1</sup>

On May 14, 2021, Donna Fulbright filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") following her receipt of an influenza ("flu") vaccine on October 7, 2020. The case was assigned to the Special Processing Unit of the Office of Special Masters.

\_

<sup>&</sup>lt;sup>1</sup> Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <a href="https://www.govinfo.gov/app/collection/uscourts/national/cofc">https://www.govinfo.gov/app/collection/uscourts/national/cofc</a>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

After review of the record and the parties' arguments, I conclude that Petitioner's shoulder pain more likely than not began within forty-eight (48) hours of vaccination, and that she has established all other requirements for a Table SIRVA. Accordingly, she is entitled to compensation.

## I. Relevant Procedural History

Petitioner summarily alleged a Table SIRVA, then filed the statutorily-required affidavit and medical records as Exs. 1 - 11 (ECF Nos. 14 - 16) roughly one year later in May 2022, as well as an Amended Petition (ECF No. 20) in August 2022. Respondent's preliminary question about the injury's onset (ECF No. 24) prompted the submission of several sworn witness declarations,  $^3$  Exs. 14 - 17 (ECF No. 26), in October 2023.

Respondent formally disputed a Table SIRVA onset in the Rule 4(c) Report filed on January 26, 2024 (ECF No. 32), and the parties' litigative risk settlement discussions reached an impasse in September 2024 (ECF No. 39). Accordingly, Petitioner and two more witnesses submitted additional sworn declarations, Exs. 18 – 20 (ECF No. 41). The parties briefed the issue. Brief filed Nov. 8, 2024 (ECF No. 43); Response Dec. 20, 2024 (ECF No. 44); Reply filed Jan. 6, 2025 (ECF No. 45). The matter is now ripe for adjudication.

#### II. Applicable Legal Standards

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule

-

<sup>&</sup>lt;sup>3</sup> See 28 U.S.C.A. § 1746 (providing that such a declaration may be afforded like force and effect as a notarized affidavit).

does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, \*4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical

records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

#### III. Evidence

I have reviewed the complete record (including all medical records, sworn declarations, both versions of the Petition, Respondent's Rule 4 Report, and both parties' briefing), and highlight the following:

- Medical Records. The at-issue vaccine was administered in Petitioner's right arm on October 7, 2020, at her workplace in North Carolina. Ex. 1 at 3 and Ex. 13 (certified records and letter from CVS).
- Petitioner was at the time 49 years old, with no history of shoulder pain or dysfunction. Ex. 6 at 5 – 8; Ex. 4 at 6. She had seen a chiropractor for back and neck pain periodically, most recently back in April 2020. Ex. 6 at 78 – 80.
- On November 5, 2020, the chiropractor recorded that in addition to ongoing back and neck pain, Petitioner's right shoulder "ha[d] been bothering her for about 2 – 3 weeks." Ex. 6 at 81; see also id. at 84 – 86 (November 12<sup>th</sup> follow-up not addressing onset).
- Almost a month later, on December 1, 2020, Petitioner attended a primary care appointment conducted by a nurse practitioner ("NP"). The appointment's reasons included: "Shoulder pain present since flu vacc admin. at work Oct. 7<sup>th</sup>." Ex. 4 at 13. The history of present illness states: "Started about mid-October... Unable to lift right shoulder above head... No recent injuries. She is still working but only using her left arm to get her job done." *Id.* After confirming the injury on physical examination, the NP prescribed pain medications and entered an orthopedics referral.
- At the December 2, 2020 orthopedics initial evaluation, a physician's assistant ("PA") recorded: "[R]ight shoulder pain and stiffness which began in mid-October. She is unaware of any antecedent injury but notes that her discomfort and stiffness began shortly after receiving her annual flu shot." Ex. 2 at 117. The PA tentatively assessed mild adhesive capsulitis and subacromial bursitis, for which he recommended continuing pain medications, and starting physical therapy ("PT") at within the same orthopedics practice. *Id.* at 118.
- The December 7, 2020 PT initial evaluation record reflects an onset of "10/2020," as well as: "R shoulder pain and stiffness that began a few months ago of insidious onset... symptoms started following flu shot, but not sure if that is correlated...

denies any history of R shoulder injury... pain being worse at night time... gradual worsening in movement over time." Ex. 2 at 112.

- On December 23, 2020, the orthopedics PA recorded that Petitioner was suffering from "right shoulder adhesive capsulitis that occurred after receiving her flu shot in October," treated that day with a steroid injection. Ex. 2 at 92.
- On January 20, 2021, a primary care PA recorded that Petitioner had been dealing with right shoulder pain and decreased ROM, which "may have been contributed by her influenza vaccine causing inflammatory response in the joint," according to Petitioner and/or her specialists. Ex. 4 at 10.
- On February 3, 2021, the orthopedics PA maintained the same history, and added that Petitioner's right shoulder had "failed conservative treatment" (PT plus oral and injected steroids), and thus she would undergo surgical manipulation under anesthesia. Ex. 2 at 71.
- At a February 10, 2021, initial evaluation and pre-operative appointment, an orthopedist recorded that Petitioner had "right shoulder pain and stiffness since mid-October that began shortly after her flu vaccination." Ex. 3 at 15; see also Ex. 2 at 182 83 (February 15<sup>th</sup> operative note).
- The post-operative PT records state that "in 10/2020 [Petitioner] started having pain in the R shoulder following a flu shot." See, e.g., Ex. 2 at 67.
- On April 26, 2021, an orthopedic surgeon recorded that Petitioner's right shoulder pain "[has] been ongoing since October 2020," and arthroscopic surgery was recommended. Ex. 2 at 12 – 13; see also Ex. 5 at 18 (MRI report, not addressing onset).
- On May 11, 2021, a second orthopedic surgeon (at a different practice from the aforementioned providers) recorded that Petitioner had been "experiencing a stiff shoulder for about 7 months... began after she received a flu shot in 10/2020." Ex. 5 at 19. This provider also recommended arthroscopic surgery, which Petitioner underwent on June 10, 2021. Ex. 5 at 20; Ex. 7 at 8 9. No further records address onset.
- Affidavits. Petitioner maintains that the October 7, 2020 flu vaccine's administration caused "immediate" pain, which worsened that night and in subsequent days. Ex. 11 at ¶ 2; Ex. 14 at 2; Ex. 18 at ¶¶ 1 − 2. She states that the November 5, 2020 chiropractic appointment was primarily for her back, so she

"wasn't focused on [her] shot, or on giving an exact timeline of shoulder pain to [her] chiropractor at the time." Ex. 18 at ¶ 6.4 She adds that the medical record notations such as "mid-October" and "insidious" might refer to her "pain and decreased use of her shoulder continu[ing] to become worse" in the weeks after October 7th. *Id.* at ¶ 7.

- Petitioner's husband "remember[s] her waking me up in the middle of the night after getting the flu shot at work that day," and her pain persisting over the following days and weeks. Ex. 15 at ¶¶ 1-2.
- A friend recalls that sometime in "the fall of 2020," she observed that Petitioner "barely had use of her right arm," and Petitioner recounted that she had been injured by a flu shot "a couple of days prior." Ex. 17 at ¶ 1. During this encounter, the friend encouraged Petitioner to see a doctor and perhaps try using a TENS unit for pain. Id. at ¶ 2.
- One coworker explains that their shared employer (a furniture store) offers yearly flu shots, and that Petitioner accepted one on October 7, 2020. Ex. 16 at ¶ 1. Petitioner began complaining of pain in her vaccinated right arm the next day, and the pain never went away and only seemed to get worse. Id. at ¶ 2. Even though Petitioner is left-handed, it was still difficult to do her job, as she was in a great amount of pain and could not lift her right arm. Id. at ¶ 3.
- A second coworker recalls Petitioner complaining of shoulder and arm pain starting the day after the vaccination. Ex. 19 at ¶ 2. Within a week, she was losing motion of the shoulder and was in a great deal of pain. Id. at ¶ 3. This coworker helped her Petitioner with job responsibilities including "mov[ing] things from station to station in buggies that are very heavy," as well as putting her hair up each day. Id.
- A third coworker recalls receiving her own flu shot alongside Petitioner on October 7, 2020. Ex. 20 at ¶ 2. The next day, Petitioner asked if the coworker had the same pain that she was experiencing. Id. at ¶ 3. Within days later, Petitioner was having trouble moving her right shoulder. Id.

<sup>4</sup> Petitioner also states at their second post-vaccination appointment – i.e., on November 12, 2020 – the chiropractor "suggested adhesive capsulitis." Ex. 11 at ¶ 2. This is not documented in the

contemporaneous record, Ex. 6 at 84 - 86.

## IV. Analysis

The sole disputed issue bearing on entitlement for a Table SIRVA is whether Petitioner's right shoulder pain began within forty-eight (48) hours of her October 7, 2020 vaccination. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii).

In challenging this criterion, Respondent argues that the medical records from several different providers "consistently document two specific facts as to onset: 1) that [Petitioner's] pain began sometime after her vaccination, and 2) her symptoms most likely began one week after vaccination on, or about, October 15, 2020." Response at 8-9. Respondent notes that at least four separate medical providers took down Petitioner's history of shoulder pain as existing since "mid-October," or two to three weeks prior to November  $5^{th}$  (meaning October  $15^{th}$  at the earliest). *Id.* at 10. Respondent also argues that not even Petitioner's own affidavits support that she suffered a particular "worsening" at this later point in time. Response at 10-11.

Petitioner admits that these notations were not made with "laser-like precision," Brief at 11, or "exactitude," but contends that the onset date could still arguably reach back to October 7<sup>th</sup>, 8<sup>th</sup>, or 9<sup>th</sup>. Reply at 4. And the same records (apart from that of the chiropractor, who was accustomed to treating her chronic unrelated concerns) reflect that the shoulder pain had been present "since," "shortly after," and "following" the vaccination. Within the Program, such terms are typically understood to "mean *very* close in time – immediately, or at most within a day or two" after vaccination. *Flowers v. Sec'y of Health & Hum. Servs.*, No. 20-285V, 2024 WL 2828211, at \*11 (Fed. Cl. Spec. Mstr. May 8, 2024), *mot. for rev. den'd*, 173 Fed. Cl. 613 (2024). Thus, while there is evidence in this record unsupportive of a timely onset, the balance of proof favors Petitioner on this disputed matter.

The supporting witness statements were prepared several years after the events in question, after Respondent questioned onset, and in support of Petitioner's claim – all factors suggesting they might be properly given less weight than contemporaneous record proof from Petitioner's treatment history. Nonetheless, the statements are all sworn under penalty of perjury – and are not properly disregarded entirely, simply due to the circumstances of their creation. Brief at 14, citing *James-Cornelius v. Sec'y of Health & Hum. Servs.*, 984 F.3d 1374, 1380 (Fed. Cir. 2021) (stating that "sworn testimony as to facts within the witnesses' personal knowledge, such as the receipt of a vaccine and the timing and severity of symptoms" constitutes objective evidence). And here, Petitioner's three coworkers (who have no obvious stake in this litigation) describe receiving vaccines alongside her on October 7, 2020. These coworkers were subsequently tangibly impacted by Petitioner's injury because they had to assist her and take over certain work tasks. For

those reasons, the coworkers' sworn statements are particularly compelling, and help to tip the onset determination in her favor. Accordingly, Petitioner has established an onset of shoulder pain within 48 hours post-vaccination, consistent with a Table SIRVA.

#### **Conclusion and Scheduling Order**

Respondent does not raise any other objections to entitlement, see generally Rule 4(c) Report. He was obligated to have done so pursuant to Vaccine Rule 4(c) (stating that the Rule 4(c) Report "must... contain Respondent's medical analysis of Petitioner's claims and must present *any* legal arguments that Respondent may have in opposition to the petition") (emphasis added).

Based on my independent review, I find that Petitioner has preponderantly established all requirements for a Table SIRVA claim. 42 C.F.R. § 100.3(c)(10). Accordingly, she need not prove causation-in-fact. Section 11(c)(1)(C). I also find that Petitioner has satisfied all other statutory requirements including a sufficiently severe injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).

For the foregoing reasons, I find that Petitioner has established entitlement and is thus entitled to compensation for a right-sided Table SIRVA following her October 7, 2020 flu vaccine administration.

The case is now formally in the damages phase. The parties are encouraged to pursue informal resolution of an appropriate damages award. Petitioner has represented (while updating the Court on the parties' earlier settlement discussions) that her demand was limited to past pain and suffering and past unreimbursable expenses, and that the case does not involve a Medicaid lien. ECF No. 31. If the parties determine that informal resolution is not possible, they should be prepared to promptly brief the appropriate award of damages.

By no later than Monday, May 12, 2025, Petitioner shall file a Status Report updating on the parties' efforts towards informally resolving damages.

IT IS SO ORDERED.

s/Brian H. CorcoranBrian H. CorcoranChief Special Master